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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,372	12/21/2001	Roger A. Sabbadini	078853-0302	3592

30542 7590 08/29/2006

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EXAMINER

GITOMER, RALPH J

ART UNIT PAPER NUMBER

1655

DATE MAILED: 08/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/029,372

Applicant(s)

SABBADINI, ROGER A.

Examiner

Ralph Gitomer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 15-17, 19 and 21-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 15-17, 19 and 21-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Applicant's election without traverse of Group I, claims 1-8, 15-17, 19, 21-28, in the reply filed on 6/20/06 is acknowledged. Please inform the examiner of any related cases, abandoned, pending or allowed. And please update the continuing information in the specification. Priority is granted to 12/22/2000.

The claimed invention appears to be directed to the nexus between the sphingolipid pathway and any cardiovascular or cerebrovascular disease. All the compounds claimed are known for affecting this pathway and have citations to that effect in the specification. Many of the claimed compounds are well known to be administered to humans for a variety of reasons and any effect derived from such administration would be inherent in the administration..

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-8, 15-17, 19, 21 are rejected under 35 U.S.C. 102(a) as being anticipated by each of Gamble and Tabas.

Gamble (6,649,362) entitled "Screening Method for an Agent Having an Effect on a Sphingosine Kinase Signaling Pathway" teaches in column 5 last paragraph bridging to column 6, modulating activity of sphingosine kinase pathway can be by competition with substrates such as sphingosine or ATP, interference with the catalytic activity of

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sphingosine kinase or interfering with enzyme activation. In column 6 lines 29-36, the pathway includes ceramide, Sph-1-P, protein kinase C. In column 7 lines 27-34, modulation is performed by administering an agent to a mammal the modulates synthesis of components, functions as an antagonist or agonist to components of the pathway. In column 11 last full paragraph, the present invention can be used as a prophylactic or a therapy for conditions such as coronary heart disease. See the claims.

Tabas (6,613,322) entitled "Method for Treating a Subject Suffering from Conditions Associated with an Extracellular Zinc Sphingomyelinase" teaches in column 8 last paragraph conditions treated include atherosclerotic vascular disease, coronary artery disease, and cerebral vascular disease. In column 9 first full paragraph, the inhibitor may be a peptide or polypeptide, a peptidomimetic compound, an organic compound, an nucleic acid, an inorganic compound or an antibody. The inhibitor inactivates zinc sphingomyelinase.

All the features of the claims are taught by each of the above references for the same function as claimed.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 22-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of each of Gamble and Tabas in view of applicants admissions in the specification.

See the teachings of Gamble and Tabas above

The claims differ from the above references in that they specify the compounds which inhibit the enzymes.

The specification teaches each of the claimed compounds is known to inhibit the respective enzymes.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to administer the claimed compounds to modulate the sphingosine pathway to treat vascular disease in view of the primary references because the specification teaches the claimed compounds are known to modulate the sphingosine pathway. The nexus between vascular disease and the sphingosine pathway is clearly described in the primary references above.

Further, some of the claimed compounds such as sodium fluoride, propranolol, and others are known to be administered to humans for various reasons and treating vascular disease would have been inherent in administering the same compounds for any reason.

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8, 15-17, 19, 21-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claims 1 and all occurrences, "wherein said agent is not an aminoglycoside" is new matter. This concept is not found in the specification as originally filed.

Claims 1-8, 15-17, 19, 21-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification does not reasonably provide enablement for preventing cardiovascular or cerebrovascular disease in a mammal by administering an agent as claimed. No data is presented regarding prevention.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8, 15-17, 19, 21-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

In claim 1 line 2, "the activity" lacks antecedent basis. All dependent claims should begin with a definite article. In claim 2 line 2, "thereto" is unclear as to whom it is administered.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Liotta (6,610,835) teaches sphingolipid derivatives for treating conditions.

Sabbadini (6,858,383, 6,881,546) are related patents.

Siess (IUBMB Life) teaches sphingosine and cardiovascular disease.

Yu (J of Molecular Neuroscience) teaches sphingomyelinase and stroke.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Ralph Gitomer
Primary Examiner
Art Unit 1655

RALPH GITOMER
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GROUP 1200